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10	UNITED STATES DISTRICT COURT				
11	SOUTHERN DISTRICT OF CALIFORNIA				
12 13	KENTON L. CROWLEY, et	al	) Civil No. 00	-cv-641-L(BGS	4
14	Plaintiff	· · · · · · · · · · · · · · · · · · ·	ORDER:	-CV-041-L(DOS	,)
15			Ó	NG PLAINTIF	FS'
16	v.	•	) MOTION T ) [DOC. 57], ,	O AMEND CO	OMPLAINT
17	EPICEPT CORPORATION,		) (2) GRANT	ING DEFEND	
18	Defenda	int.	) MOTION F ) JUDGMEN	OR SUMMAF T [DOC. 50]	RY
19	On December 1, 2008, Plaintiffs Kenton L. Crowley and John A. Flores commenced this				
20	action against Defendant Epicept Corporation. This action involves the circumstances				
21	surrounding an agreement whereby Plaintiffs assigned two patents to Defendant for				
22	development. Defendant now moves for summary judgment, and Plaintiffs concurrently move				
23	to amend their complaint. Both motions are opposed.				
24	The Court found these motions suitable for determination on the papers submitted and				
25	without oral argument. See Civ. L.R. 7.1(d.1). (Docs. 69, 80.) For the following reasons, the				
26	Court <b>DENIES</b> Plaintiffs' motion to amend the complaint (Doc. 57), and <b>GRANTS</b> Defendant's				
27	motion for summary judgment. (Doc. 50.)				
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### I. BACKGROUND

Between 1998 and 2000, Dr. Crowley, a pharmacist, and Dr. Flores, a physician, jointly obtained two patents. (Crowley Decl. ¶ 2–3.) The first is U.S. Patent No. 5,817,699, entitled "Patent For Process For The Preparation of Ketamine Ointment," and the second is U.S. Patent No. 6,017,961, entitled "Ketamine and N-Butyl-P-Aminobezoate in PLO." (*Id.*) These patents, collectively referred to as the Crowley Flores Patents, <sup>1</sup> provide a topical treatment for neuropathic and other forms of pain and other diseases, such as Parkinson's Disease. (*Id.* ¶ 6.) Prior to the Crowley Flores Patents, the only commercially available forms of ketamine were through intravenous, subcutaneous, or intramuscular injection. (*Id.* ¶ 7.) These commercially available applications were known to have side effects such as sedative and cognitive impairment. (*Id.*)

## A. Assignment Agreement

On December 1, 2000, the parties entered into an Assignment Agreement. (Talley Decl., Ex. B.) The Agreement was negotiated between Dr. Crowley and Peter Golikov, who was Defendant's President and Chief Operations Officer at the time. (Crowley Dep. 82:4–86:14; Golikov Dep. 205:10–206:1.) Dr. Crowley does not believe that Mr. Golikov made any false representations or failed to disclose any information during the negotiations. (Crowley Dep. 290:12–16, 297:19–298:6.) Both sides were assisted by outside counsel. (Crowley Dep. 86:3–12; Golikov Dep. 205:10–206:1.) Furthermore, Defendant entered the Agreement planning to develop a commercial product based on Plaintiffs' patents. (Golikov Dep. 111:18–119:8.) Though Mr. Golikov never discussed with Dr. Crowley that Defendant may stop development of NP-2 altogether, Dr. Crowley knew that there was a possibility that the FDA would not approve NP-2. (Golikov Dep. 241:5–16; Crowley Dep. 154:7–15.)

<sup>&</sup>lt;sup>1</sup> U.S. Patent No. 5,817,699 is individually referred to as the "699 Patent." U.S. Patent No. 6,017,961 is individually referred to as the "961 Patent." "NP-2" refers to Plaintiffs' ketamine-butamben drug candidate; "NP-1" refers to Defendant's ketamine-amitriptyline drug candidate that it began developing in 2000. (Talley Decl. ¶¶ 4–5, 24.)

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The Agreement provides that "Crowley and Flores each does hereby assign to EpiCept his entire right, title and interest in and to the Invention, any Improvements, and the [Crowley Flores] Patents." (Agreement § 2.) It further provides that Plaintiffs shall provide written notice to Defendant of each improvement within thirty days of the date of conception or, if conceived prior to the effective date, then within ten days after the effective date. (*Id.* § 2.1.) In consideration for the rights granted by the assignment, Defendants were to pay Plaintiffs an assignment fee of \$300,000, and royalties beginning on the date of the first commercial sale, continuing for a set time period. (*Id.* § 4.1–4.2.)

The Agreement also contains language for termination of the assignment if there is a material breach. Specifically, if there is a material breach by Defendant:

[Plaintiffs] shall have the right to terminate this Agreement pursuant to this Section 10.2 only if (a) EpiCept material breaches the payment obligations set forth in Section 4 hereof; or (b) EpiCept fails to use commercially and scientifically reasonable efforts to (i) file an Investigational New Drug Application, or its equivalent, with the United States Food and Drug Administration ("FDA"), directed to a Patented Product within two (2) years of the Effective Date hereof, or (ii) file a New Drug Application, or its equivalent, with the FDA directed to a Patented Product within four (4) years of the Effective Date hereof, provided that EpiCept and [Plaintiffs] agree to renegotiate, in good faith, the terms of this Section 10.2.1(b) at any time upon the request of EpiCept. If [Plaintiffs] duly terminate this Agreement pursuant to this Section 10.2.1, EpiCept shall execute an Assignment . . . transferring EpiCept's entire right, title, and interest in and to the Patents to [Plaintiffs], jointly.

Patents to [Plaintiffs], jointly. (Agreement § 10.2.1.) If there is a material breach by Plaintiffs, "EpiCept shall have the right to terminate this Agreement pursuant to this Section 10.2 only if one or both of [Plaintiffs] material breach (a) the confidentiality obligations . . . and/or (b) the terms and conditions of Section 7." (*Id.* § 10.2.2.) In the event of a material breach, the non-breaching party must provide written notice and an election to terminate at the expiration of a 90-day cure period. (*Id.* § 10.2.3.) The non-breaching party may terminate by giving a second written notice should the breaching party fail to: (1) cure the default, (2) provide a satisfactory written explanation that a default has not occurred, or (3) enter into a written agreement resolving the default. (*Id.*)

Lastly, the Agreement contains an integration clause and a New Jersey choice-of-law provision. (Agreement §§ 13.3, 13.6.)

# **B.** Performance Under the Agreement

Around the time that the parties entered into the Agreement, Dr. Flores used the ketamine-butamben ointment to treat his patients for pain who had first-degree and second-degree burns. (Flores Dep. 46:6–51:23.) He found the ointment effective in treating the pain associated with such burns. (*Id.*) However, the treatment of pain associated with first-degree and second-degree burns is not a claim or an indication of the '961 Patent. (Talley Decl. ¶ 28.) Furthermore, Plaintiffs did not inform Defendant that they used the ketamine-butamben ointment to treat Dr. Flores' patients suffering from first-degree and second-degree burns. (*Id.* ¶ 26; Flores Dep. 51:2–4.)

Pursuant to the Agreement, Defendant paid Plaintiffs the \$300,000 assignment fee. (Golikov Dep. 111:18–112:6; Crowley Dep. 289:8–21.) When Defendant began developing NP-2, it also hired Dr. Crowley as a paid consultant to assist in the process. (Dr. Crowley Dep. 102:15–103:13, 182:1–185:4, 250:14–16.) Defendant worked directly on developing NP-2 for a year. (Talley Decl. ¶¶ 2–19.) During that year, Defendant conducted formulation, stability, and permeation studies to further develop NP-2 in an effort to submit an Investigational New Drug ("IND") Application to the FDA. (*Id.* ¶¶ 6, 10; Crowley Dep. 182:2–188:1.) In fact, Dr. Crowley was directly involved in some of the pre-clinical studies, and agreed that Defendant performed as expected during the first year or two. (Crowley Dep. 182:2–188:1, 289:8–25, 298:7–12.)

After finishing the three studies, Defendant decided to prioritize its development efforts of NP-1 over NP-2. (Talley Decl., Ex. A.) It explained to Plaintiffs that the decision was made due to "limited resources" and the belief that "the scientific information gained from the development of NP-1 would greatly enhance the chances of success for another ketamine-based product [such as NP-2]." (*Id.*) Defendant also informed Dr. Crowley that it believed that it would be easier to obtain FDA approval for NP-1. (Crowley Dep. 320:4–14.) This concern was particularly important because sometime after entering into the Agreement, the FDA expressed concerns to Defendant about the topical use of ketamine in NP-1 and informed Defendant that it would not allow Defendant to rely upon safety studies that the FDA already had supporting

ketamine. (Talley Decl. ¶ 14.) According to Defendant, it also postponed direct development of NP-2 because Plaintiffs' technology was inferior to a cream version of NP-2 and Plaintiffs' technology as reflected in the '961 Patent could not be commercialized because the patented formula was not stable enough for FDA approval. (Golikov Dep. 133:22–138:4, 219:16–221:24.) By October 2001, all development work on NP-2—both preclinical and clinical—had ended. (Talley Dep. 93:8–94:1.)

In November 2002, Defendant acknowledged in a letter to Plaintiffs that it was not going to file an IND application by December 1, 2002, but wrote that it had "every intent to do whatever is necessary to eventually file an IND, and later an NDA [or "New Drug Application"] directed at a Patented product" and "look[ed] forward to continuing this relationship." (Larson Decl., Ex. B.) The purpose of this letter was to assure Dr. Crowley that work was proceeding on NP-2. (Kozak Dep. 74:6–12.) Thereafter, in September 2003, an email was sent to Dr. Crowley stating that "[a]s we stated in our June 2003 email, we will keep you involved in the IND process and development for NP-2 as we move the project forward." (Larson Decl., Ex. C.)

By January 2004, Plaintiffs began inquiring as to the status of NP-2 in order to assess whether they should terminate. (Larson Decl., Ex. D; Phillips Decl. ¶ 31.) The following month, Defendant responded to the inquiries, stating that it was in compliance with the Agreement, that it was working on NP-1 to help develop NP-2, and that it had every intention of filing an IND application and NDA for NP-2. (Larson Decl., Ex. E; Phillips Decl. ¶ 32.) In March 2004, through their counsel, Plaintiffs advised Defendant in writing that they were not satisfied with the update given. (Larson Decl., Ex. G; Phillips Decl. ¶ 32.) Shortly thereafter, Defendant responded that: (1) Defendant believed that its ketamine work will help the company in submitting NP-2 to the FDA; (2) Defendant has a meeting set up with the FDA to help guide the company in its development efforts of ketamine; (3) after that meeting, Defendant may have a basis for submitting an IND application for NP-2; and (4) Defendant's executives looked forward to a continuing relationship with Plaintiffs and meeting Dr. Crowley in New York. (Larson Decl., Ex. H; Phillips Decl. ¶ 33.)

On May 18, 2004, Plaintiffs received a letter proposing a termination agreement in which

Defendant retained licensing rights. (Larson Decl., Ex. J; Phillips Decl. ¶¶ 13–16, 36.)

Plaintiffs rejected the proposal. (*Id.*) In addition to rejecting the proposal, they suggested that no work had been done on NP-2 since 2001, when Dr. Crowley stopped consulting for Defendant, and demanded a cure in accordance with the Agreement. (*Id.*) It is unclear what

immediately transpired next, but Plaintiffs contend that Defendant refused to terminate without

retaining licensing rights. (Phillips Decl. ¶ 37.) Then in April 2006, Plaintiffs terminated the Agreement due to "[Defendant's] failure to abide by the terms of Section 10.2.1" and demanded

that Defendant assign the patents back to Plaintiffs. (Larson Decl., Ex. K.)

For next year, Plaintiffs continuously inquired about the termination, but to no avail. (Phillips Decl. ¶¶ 41–42, 44, 46–47.) Other companies approached Plaintiffs concerning the licensing of the patents, but became disinterested when learning that Defendant had not reassigned the patents back to Plaintiffs. (Crowley Decl. ¶ 26.)

On December 1, 2008, Plaintiffs commenced this action. In the complaint, they assert four claims: (1) breach of contract, (2) breach of implied covenant of good faith and fair dealing, (3) fraud, and (4) rescission. Defendant now moves for summary judgment, and Plaintiffs concurrently move to amend their complaint. Both motions are opposed.

#### II. MOTION TO AMEND COMPLAINT

#### A. Legal Standard

Rule 15(a) of the Federal Rules of Civil Procedure provides that after a responsive pleading has been served, a party may amend its complaint only with the opposing party's written consent or the court's leave. Fed. R. Civ. P. 15(a). "The court should freely give leave when justice so requires" and apply this policy with "extreme liberality." *Id.*; *DCD Programs, Ltd. v. Leighton*, 833 F.2d 183, 186 (9th Cir. 1987). However, leave to amend is not to be granted automatically. *Zivkovic v. S. Cal. Edison Co.*, 302 F.3d 1080, 1087 (9th Cir. 2002) (citing *Jackson v. Bank of Haw.*, 902 F.2d 1385, 1387 (9th Cir. 1990)). Granting leave to amend rests in the sound discretion of the district court. *Pisciotta v. Teledyne Indus., Inc.*, 91 F.3d 1326, 1331 (9th Cir. 1996).

The Court considers five factors in assessing a motion for leave to amend: (1) bad faith, (2) undue delay, (3) prejudice to the opposing party, (4) futility of the amendment, and (5) whether the plaintiff has previously amended the complaint. *Johnson v. Buckley*, 356 F.3d 1067, 1077 (9th Cir. 2004). Of these factors, prejudice to the opposing party carries the greatest weight. *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003). However, absent prejudice, a strong showing of the other factors may support denying leave to amend. *See id.*; *Allen v. City of Beverly Hills*, 911 F.2d 367, 373 (9th Cir. 1990) (holding that futility supports a court's decision to deny a motion for leave to amend).

Futility is a measure of the amendment's legal sufficiency. "[A] proposed amendment is futile only if no set of facts can be proved under the amendment . . . that would constitute a valid and sufficient claim or defense." *Miller v. Rykoff-Sexton, Inc.*, 845 F.2d 209, 214 (9th Cir. 1988). Thus, the test of futility is identical to the one applied when considering challenges under Rule 12(b)(6) for failure to state a claim upon which relief may be granted. *Baker v. Pac. Far East Lines, Inc.*, 451 F. Supp. 84, 89 (N.D. Cal. 1978); *see Saul v. United States*, 928 F.2d 829, 843 (9th Cir. 1991) ("A district court does not err in denying leave to amend . . . where the amended complaint would be subject to dismissal." (citation omitted)).

## B. Discussion

Plaintiffs seek to amend their complaint in order to clarify the nature and scope of two of their claims—breach of contract and fraud—and the relief sought in light of new information gathered during discovery. (Am. Mot. 2:3–18 [Doc. 57].) To support their motion, they argue that the delay outside the original scheduling order in seeking an amendment is "justified" and "for good cause," and that there is no undue burden to Defendant. (*Id.* at 15:2–3, 18:13.) In response, Defendant argues: (1) Plaintiffs seek to amend with undue delay, (2) amending the complaint would prejudice Defendant, (3) amending the complaint would be futile because the facts and law do not support the proposed claims, and (4) the motion lacks any factual support. (Am. Opp'n 2:4, 3:13, 4:16–17, 9:2.) In their reply, Plaintiffs only address the undue-burden issue, and add that Plaintiffs did not engage in any dilatory conduct. (Am. Reply 9:11–12,

10:7-8.)

Though prejudice is the most important factor in assessing whether to grant leave to amend a complaint, courts have denied plaintiffs leave to amend their complaints when the proposed amendment is found to be futile. *See Coleman v. Sterling*, No. 09-CV-1594, 2011 WL 839552, at \*3 (S.D. Cal. Mar. 7, 2011) (Whelan, J.). Here, Plaintiffs wholly fail to address Defendant's argument that their proposed amendment is futile. In fact, their motion only references futility twice, while presenting the legal standard for amending complaints (Am. Mot. 13:16, 15:7), and their reply also only references futility twice, once while presenting the legal standard and once while summarizing Defendant's argument (Am. Reply 7:18, 9:16). By not presenting any factual support or legal analysis in response to Defendant's argument that the proposed amendment is futile, Plaintiffs effectively concede that their proposed amendment is indeed just that, futile.

Accordingly, the Court **DENIES** Plaintiffs' motion to amend their complaint.

# III. DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

#### A. Legal Standard

Summary judgment is appropriate under Rule 56(c) where the moving party demonstrates the absence of a genuine issue of material fact and entitlement to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A fact is material when, under the governing substantive law, it could affect the outcome of the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *Freeman v. Arpaio*, 125 F.3d 732, 735 (9th Cir. 1997). A dispute about a material fact is genuine if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson*, 477 U.S. at 248.

A party seeking summary judgment always bears the initial burden of establishing the absence of a genuine issue of material fact. *Celotex*, 477 U.S. at 323. The moving party can satisfy this burden in two ways: (1) by presenting evidence that negates an essential element of the nonmoving party's case; or (2) by demonstrating that the nonmoving party failed to make a showing sufficient to establish an element essential to that party's case on which that party will

bear the burden of proof at trial. *Id.* at 322-23. "Disputes over irrelevant or unnecessary facts will not preclude a grant of summary judgment." *T.W. Elec. Serv., Inc. v. Pac. Elec. Contractors Ass* 'n, 809 F.2d 626, 630 (9th Cir. 1987).

"The district court may limit its review to the documents submitted for the purpose of summary judgment and those parts of the record specifically referenced therein." *Carmen v. San Francisco Unified Sch. Dist.*, 237 F.3d 1026, 1030 (9th Cir. 2001). Therefore, the court is not obligated "to scour the record in search of a genuine issue of triable fact." *Keenan v. Allen*, 91 F.3d 1275, 1279 (9th Cir. 1996) (citing *Richards v. Combined Ins. Co. of Am.*, 55 F.3d 247, 251 (7th Cir. 1995)). If the moving party fails to discharge this initial burden, summary judgment must be denied and the court need not consider the nonmoving party's evidence. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 159-60 (1970).

If the moving party meets this initial burden, the nonmoving party cannot defeat summary judgment merely by demonstrating "that there is some metaphysical doubt as to the material facts." *Matsushita Electric Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986); *Triton Energy Corp. v. Square D Co.*, 68 F.3d 1216, 1221 (9th Cir. 1995) ("The mere existence of a scintilla of evidence in support of the nonmoving party's position is not sufficient.") (citing *Anderson*, 477 U.S. at 242, 252). Rather, the nonmoving party must "go beyond the pleadings" and by "the depositions, answers to interrogatories, and admissions on file," designate "specific facts showing that there is a genuine issue for trial." *Celotex*, 477 U.S. at 324 (quoting Fed. R. Civ. P. 56(e)).

When making this determination, the court must view all inferences drawn from the underlying facts in the light most favorable to the nonmoving party. *See Matsushita*, 475 U.S. at 587. "Credibility determinations, the weighing of evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge, [when] he [or she] is ruling on a motion for summary judgment." *Anderson*, 477 U.S. at 255.

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#### B. Discussion

#### 1. Breach of Contract

To prevail on a breach-of-contract claim, a plaintiff must prove the following elements: (1) a valid contract existed between plaintiff and defendant; (2) defendant breached the contract; (3) plaintiff performed its obligations under the contract; and (4) plaintiff was damaged as a result of the breach. *Video Pipeline, Inc. v. Buena Vista Home Entm't*, 275 F. Supp. 2d 543, 566 (D.N.J. 2003) (citing *Nat'l Util' Serv., Inc. v. Chesapeake Corp.*, 45 F. Supp. 2d 438, 448 (D.N.J. 1999); *Coyle v. Englander's*, 199 N.J. Super. 212, 223 (App. Div. 1985)). Defendant argues that Plaintiffs failed to perform their obligations to notify Defendant of an improvement to the patents as required by the Agreement, and that consequently precludes relief that Plaintiffs seek. Plaintiffs respond that there was no such improvement.

"[A] court will, if possible, give effect to all parts of the instrument, and an interpretation which gives a reasonable meaning to all its provisions will be preferred to one which leaves a portion of the writing useless or inexplicable." *Maryland Cas. Co. v. Hansen–Jensen, Inc.*, 15 N.J. Super. 20, 27 (App. Div.1951). Although it is not admissible to "vary the terms of the contract," New Jersey law permits the "broad use of extrinsic evidence to achieve the ultimate goal of discovering the intent of the parties." *Conway v. 287 Corporate Ctr. Assocs.*, 187 N.J. 259, 270 (2006). "Extrinsic evidence may be used to uncover the true meaning of contractual terms." *Id.* Such evidence may "include consideration of the particular provision, an overview of all the terms, the circumstances leading up to the formation of the contract, custom, usage, and the interpretation placed on the disputed provision by the parties' conduct." *Id.* at 269 (quoting *Kearny PBA Local # 21 v. Town of Kearny*, 81 N.J. 208, 221 (1979)) (internal quotation marks omitted).

# a. Definition of "Improvement"

There is a dispute whether Dr. Flores' use of the '961 Patent's ketamine-butamben ointment to treat burn patients was an "improvement." However, more fundamentally, there is uncertainty regarding the definition of "improvement." Under the "Definitions" section of the

Agreement,

"[i]mprovements" means and includes any modification of the Invention that is, on or after the Effective Date, or was, prior to the Effective Date, invented, conceived and/or reduced to practice by Crowley and/or Flores, provided such modification or the use thereof would, if unlicensed, infringe United States Patent No. 5,817,699 and/or United States Patent No. 6,017,961.

(Agreement § 1.3.) The wording of this definition is convoluted. However, Plaintiffs understand this provision to restrict improvements "to the type of conditions that would infringe upon the [patents]." (Summ. J. Opp'n 18:9–10 [Doc. 64].) A cursory reading of this provision supports Plaintiffs' interpretation. But upon closer inspection, Plaintiffs' interpretation also produces an absurd outcome.

Presumably, any improvement is a condition that was not contemplated in the original patent—something that is not included in or covered by the original patent. Based on Plaintiffs' interpretation, if an improvement is a condition that would infringe upon the original patent but is not included in or covered by that patent, then producing an improvement is impossible. In other words, a condition that is not included in or covered by the patents cannot infringe upon the patents. Thus, Plaintiffs' interpretation renders the improvements provision useless and inexplicable. This absurd outcome leads the Court to consider the definition of "improvement" in the context of the whole agreement as well as undisputed extrinsic evidence in order uncover the true meaning of this contractual term. *See Conway*, 187 N.J. at 269-70.

Section 2.1 of the Agreement requires Plaintiffs to notify Defendant and then promptly execute an assignment for each improvement. (Agreement § 2.1.) Read together with the Agreement's definition of "improvement," it appears that the definition contemplates that the requirements of § 2.1 have been completed. This would explain the last clause of the definition—"provided such modification or the use thereof would, if unlicensed, infringe [the Crowley Flores Patents]"—in a manner that does not produce a useless or inexplicable interpretation. The result would then be unlicensed use of improvements once assigned would then infringe upon the Defendant's rights to the patents, which would include and cover "any modification of the Invention that is . . . invented, conceived and/or reduced to practice."

This interpretation is also consistent with Mr. Golikov's undisputed deposition testimony. He testified that "the reason for [the assignment of improvements] is you don't want to do a deal and find out your inventor did something better and went off in a different course, and you're stuck with something that's not good." (Golikov Dep. 236:4–8.) The assignment of improvements is a provision included to protect Defendant. Reading the definition of "improvement" in isolation as Plaintiffs do does not produce this goal, but reading it in the context of the whole agreement does. Moreover, Plaintiffs do not provide any evidence to contradict this interpretation.

Therefore, "improvement" as defined in the Agreement reasonably means and includes any modification of the patents that is invented, conceived and/or reduced to practice by Dr. Crowley and/or Dr. Flores.

#### b. Dr. Flores' Use of the Ketamine-Butamben Ointment

The next inquiry in the breach-of-contract analysis is to determine whether Dr. Flores' use of the ketamine-butamben ointment to treat the pain associated with first-degree and second-degree burns was an improvement under the Agreement. Defendant contends that Dr. Flores' finding that the ointment based on the '961 Patent was effective in treating the pain associated with burns is an indication that was not included in the '961 Patent, and thus it was an improvement that required Plaintiffs to notify Defendant of the improvement, which Plaintiffs failed to do. (Summ. J. Mot. 9:23–10:1 [Doc. 50].) Plaintiffs respond that there are genuine issues of material fact because Defendant misstated Dr. Flores' testimony and Rob Phillips' declaration shows that the Dr. Flores' use was not an improvement. (Summ. J. Opp'n 17:22–18:9.)

In Dr. Flores' deposition testimony, he agreed that the '961 Patent reflected certain treatments for the ketamine-butamben ointment, and thereafter he expanded the possible treatments for the drug. (Flores Dep. 47:6–12.) Specifically, he explained,

I did explore the potential use in treatment of burns, in treating pain associated with burns. I was also potentially interested in its application in, let's say, burn units for the treatment of burn victims because at that time it was kind of barbaric what they were doing . . . . And so I was looking for alternative treatment that would anesthetize the area enough where they could accomplish what they needed to do to allow new skin growth with less trauma and less risk of toxicity. And . . . when looking at the indication here, that was actually the only outside indication I looked at . . . . I actually did not have an opportunity to explore it beyond just theoretically. I did treat burns that patients were coming in using that and found the benefit in what I was discussing earlier—blocking the C fiber so there was no residual pain after the burn.

(*Id.* at 49:11–50:9.) The '961 Patent includes six indications for treatment: sympathetic mediated, neuropathic, myofascial, TMJ, osteoarthritis, and SIJ pain.<sup>2</sup> (*Id.* at 48:20–24; '961 Patent col.1 1.20–25 [Doc. 50-2].) Dr. Flores admitted that treating pain associated with burns is not an indication included in the patent, and that he pursued indications beyond those that are explained or set forth in the '961 Patent. (Flores Dep. 47:23–25, 50:17–19.) He further admitted that he did not inform Defendant of the use of the ketamine-butamben ointment to treat burns. (*Id.* at 51:2–4.)

The undisputed evidence shows that Dr. Flores improved upon the '961 Patent and failed to notify Defendant of the improvement. Even though Plaintiffs contend that the use of the ketamine-butamben ointment on burns "did not move beyond theoretical exploration in a very limited fashion," the definition of improvement includes conception, which is defined as the forming of a notion, idea, or opinion.<sup>3</sup> Here, conception occurred when Dr. Flores formed the idea to apply the ointment to burn patients. Plaintiffs also contend that Dr. Flores only used the ointment privately in his clinical practice, but that is not the issue here; and even it was, improvements include modifications reduced to practice. Rather the issue is whether Plaintiffs improved the patent and failed to notify Defendant of the improvement according to the terms of the Agreement.

<sup>&</sup>lt;sup>2</sup> "SIJ" is an acronym for "sacro-iliac joint." ('961 Patent col.1 l.8.) "TMJ" presumably is an acronym for "temporomandibular joint"; this acronym is not defined in the patent.

<sup>&</sup>lt;sup>3</sup> Conception is defined as "the act of conceiving." *Random House Webster's Unabridged Dictionary* 422 (2d ed. 1998). To conceive is "to form (a notion, opinion, purpose, etc.)" or more specifically, "to form a notion or idea of." *Id*.

Based on the undisputed evidence before the Court, Plaintiffs failed to perform their obligation under § 2.1 of the Agreement. Furthermore, Plaintiffs fail to identify any genuine issue of material fact.<sup>4</sup> Therefore, Plaintiffs cannot establish all of the elements for their breach-of-contract claim. *See Video Pipeline, Inc.*, 275 F. Supp. 2d at 566. Accordingly, the Court **GRANTS** Defendant summary judgment for breach of contract.

# 2. Breach of the Covenant of Good Faith and Fair Dealings

Every contract in New Jersey contains an implied covenant of good faith and fair dealing. Sons of Thunder, Inc. v. Borden, Inc., 148 N.J. 396, 420 (1997). "Good faith entails adherence to community standards of decency, fairness or reasonableness, and requires a party to refrain from destroying or injuring the right of the other party to receive its contractual benefits." Iliadis v. Wal-Mart Stores, 191 N.J. 88, 110 (2007) (internal citations and quotation marks omitted). "A party to a contract breaches the covenant if it acts in bad faith or engages in some other form of inequitable conduct in the performance of a contractual obligation." Black Horse Lane Assoc., L.P. v. Dow Chem. Corp., 228 F.3d 275, 288 (3d Cir. 2000).

"The party claiming breach of the covenant of good faith and fair dealing must provide evidence sufficient to support a conclusion that the party alleged to have acted in bad faith has engaged in some conduct that denied the benefit of the bargain originally intended by the parties." *Brunsick Hills Racquet Club, Inc. v. Route 18 Shopping Ctr. Assocs.*, 182 N.J. 210, 225 (2005) (internal quotation marks omitted). Bad faith may be overt or may consist of inaction, and it may include subterfuge, evasion, a lack of diligence or slacking off. *Black Horse Lane*, 228 F.3d at 288-89. Furthermore, "[a] plaintiff may be entitled to relief under the covenant if its reasonable expectations are destroyed when a defendant acts with ill motives and without any

<sup>&</sup>lt;sup>4</sup> Plaintiffs offer the opinions of their former patent attorney Rob Phillips in order to show that Dr. Flores' use of the ketamine-butamben ointment was not an improvement. (Summ. J. Opp'n 18:4–9.) However, his opinions are legal conclusions regarding improvements under the Agreement. Thus, consideration of his opinion is improper. *See Aguilar v. Int'l Longshoremen's Union Local No. 10*, 966 F.2d 443, 447 (9th Cir. 1992) (discussing that matters of law are for the court's determination and not an expert witness).

legitimate purpose." *Brunswick Hills Racquet Club*, 182 N.J. at 226 (citing *Wilson v. Amerada Hess Corp.*, 168 N.J. 236, 251 (2001)). "Moreover, a plaintiff may get relief if it relies to its detriment on a defendant's intentional misleading assertions." *Id.* (citing *Bak-A-Lum Corp. v. Alcoa Bldg. Prods.*, 69 N.J. 123, 129-30 (1976)). However, a party does not breach the covenant merely because its decision disadvantaged another party, and "contract law does not require parties to behave altruistically toward each other." *Wilson*, 168 N.J. at 251.

Defendant argues that Plaintiffs cannot identify any evidence that shows Defendant acted with an ill motive or without a legitimate purpose in delaying development of NP-2. (Summ. J. Mot. 17:8–18:18.) Plaintiffs identify several instances that they contend demonstrate genuine issues of material fact regarding bad faith, including stopping development on NP-2 ten months after the assignment, providing allegedly false reassurances, and failing to reassign the patents unconditionally to Plaintiffs from 2004 to 2007. (Summ. J. Opp'n 20:20–21:12.) However, Plaintiffs fail to explain how these instances demonstrate bad faith or produce a triable issue for a jury. To the contrary, the undisputed evidence shows that Defendant informed Plaintiffs that it postponed development of NP-2 because of financial issues and FDA concerns, and hoped to develop the patents in the future.

Furthermore, Defendant identifies abundant evidence that it used "commercially and scientifically reasonable" efforts in its endeavor to develop NP-2, such as the three studies that showed NP-2 was not commercially viable, the FDA's concerns regarding the combination of ketamine and butamben, and Defendant's limited resources. Plaintiffs do not challenge this, except to point out that Defendant did not complete formulation studies and other components necessary in the pre-clinical stages to submit an IND application. (Summ. J. Opp'n 17:11–14.) But Plaintiffs' contention puts the cart before the horse. The threshold issue to determine whether Plaintiffs can terminate the Agreement for material breach is whether Defendant failed to use "commercially and scientifically reasonable efforts" to file an IND application or an NDA. Not fulfilling some of the requirements to file an IND application or an NDA is not the same as failing to use commercially and scientifically reasonable efforts to file those applications. Plaintiffs incorrectly presume that not filing the IND application or the NDA

permits termination of the Agreement for material breach. Based on Plaintiffs' failure to substantively address whether Defendant used commercially and scientifically reasonable efforts as well as Defendant's presentation of abundant undisputed evidence on the issue, the Court finds that Defendant used commercially and scientifically reasonable efforts in its endeavor to develop NP-2 and prepare the IND application and the NDA.

The significance of the aforementioned finding is that Plaintiffs did not have sufficient grounds to invoke the termination provision of the Agreement for material breach. Section 10.2.1 provides that Defendant materially breaches if it fails to fulfill its payment obligations, or if it "fails to use commercially and scientifically reasonable efforts." There is no language in the Agreement regarding whether Plaintiffs can terminate for material breach if Defendant used commercially and scientifically reasonable efforts. Consequently, Plaintiffs were not entitled to reassignment of the patents through this provision. Defendant was within its right under the Agreement to hold onto the patents and negotiate the terms of its reassignment back to Plaintiffs, and any purported delay cannot be construed as bad faith. See Wilson, 168 N.J. at 251.

In sum, Defendant demonstrates that it used commercially and scientifically reasonable efforts to develop NP-2, and Plaintiffs fail to identify a genuine issue of material fact.

Therefore, Defendant did not engage in bad faith or some other form of inequitable conduct. *See Black Horse Lane*, 228 F.3d at 288. Accordingly, the Court **GRANTS** Defendant summary judgment for breach of the covenant of good faith and fair dealing.

## 3. Fraud

In their third claim, Plaintiffs allege fraud against Defendant. Defendant contends that Plaintiffs cannot identify a false statement, a failure to disclose, or any intent to defraud. In response, Plaintiffs attempt to defeat summary judgment by identifying purported genuine issues of material fact. The elements for common-law fraud are: (1) a material misrepresentation of a presently existing or past fact; (2) knowledge or belief by the defendant of its falsity; (3) an intention that the other person rely on it; (4) reasonable reliance thereon by the other person; and (4) resulting damages. *Gennari v. Weichert Co. Realtors*, 148 N.J. 582, 610 (1997). "The

elements of scienter, that is, knowledge of the falsity and an intention to obtain an undue advantage therefrom . . . are not essential if plaintiff seeks to prove that a misrepresentation constituted only equitable fraud." *Jewish Ctr. of Sussex Cnty. v. Whale*, 86 N.J. 619, 625 (1981).

#### a. Alleged Fraud before the Parties Entered into the Agreement

Regarding the alleged fraud that occurred before the parties entered into the Agreement, Plaintiffs identify one purported genuine issue for trial in response to Defendant's contentions: "whether the decision to shelve the Patents was made by those with the authority Mr. Golikov did not have." (Summ. J. Opp'n 21:23–22:1.) However, the relevance of Plaintiffs' contention is unclear. Plaintiffs do not explain how or why such authority is pertinent to the fraud claim. Thus, without further explanation, the Court finds that the issue identified by Plaintiffs is immaterial. *See T.W. Elec. Serv.*, 809 F.2d at 630. Plaintiffs also add that "Mr. Golikov testified that he advised the Plaintiffs that [Defendant] had the resources to develop their patents and that Dr. Crowley would not have done the deal had he not made such assurances" without any explanation regarding the importance of the testimony. (Summ. J. Opp'n at 22:2–4.) Ultimately, as Defendant points out, Plaintiffs fail to identify a specific false statement or misrepresentation before the parties entered into the Agreement. Furthermore, Plaintiffs fail to identify any specific evidence that shows that the assurances made by Mr. Golikov regarding Defendant's resources may indeed be false. In fact, it is undisputed that Defendant entered into the Agreement with the intent to develop the Crowley Flores Patents.

Therefore, Defendant successfully meets its burden by negating essential elements of the fraud-in-the-inducement claim, and Plaintiffs fail to show there is any genuine issue for trial regarding the alleged fraud that occurred before the parties entered into the Agreement. *See Celotex*, 477 U.S. at 322-24.

<sup>&</sup>lt;sup>5</sup> This exception relieving plaintiffs of some of their burdens of proof for fraud does not apply here because Plaintiffs seek relief beyond equitable remedies. *See Jewish Ctr. of Sussex Cnty*, 86 N.J. at 625.

b. Alleged Fraud after the Parties Entered into the Agreement

Plaintiffs also allege that Defendant engaged in fraud after the parties entered into the Agreement. Again, they attempt to defeat summary judgment by identifying purported genuine issues of material fact. Plaintiffs contend that "there is disputed evidence on whether each and every time [Defendant] promised it was applying for an IND it had no intention of doing so." (Summ. J. Opp'n 22:8–9.) The "disputed evidence" purportedly includes several communications that involve Jack Talley—Defendant's Chief Executive Officer and President since 2001—such as his email stating that he intended NP-2 would be a back up at best, his concession that development on NP-2 stopped before 2001, and his assurance to Dr. Crowley that Defendant was moving along towards an IND application. (*Id.* at 22:9–17; Talley Decl. ¶ 1.) However, again, the relevance of Plaintiffs' contention is unclear. Plaintiffs appear to be addressing the intent element for fraud, but the intent element is whether Defendant intended for Plaintiffs to *rely* on a material representation. *See Gennari*, 148 N.J. at 610. Intent to follow through or not follow through with a promise is irrelevant to the fraud analysis. *See id.* 

Regardless, it is undisputed that Defendant informed Plaintiffs in November 2002 that it was not going to file an IND application but intended to eventually file an IND. Plaintiffs fail to identify specific evidence that suggests Defendant later intended otherwise. Viewing all inferences in favor of Plaintiffs, their list of "disputed evidence" fails to show that Defendant intended that they rely on any purported misrepresentations. *See Matsushita*, 475 U.S. at 587.

In conclusion, Defendant demonstrates that Plaintiffs failed to establish all the essential elements for fraud, and Plaintiffs fail to identify a genuine issue of material fact.<sup>6</sup> *Celotex*, 477 U.S. at 322-23. Accordingly, the Court **GRANTS** Defendant summary judgment for fraud.

<sup>&</sup>lt;sup>6</sup> Plaintiffs also contend that Defendant's assurances regarding good-faith negotiations is also "disputed evidence." (Summ. J. Opp'n 22:15–17.) But this is outside the alleged fraudulent conduct stated in the complaint. (*See* Compl. ¶¶ 70–81.) Moreover, Plaintiffs also fail to explain the relevance of their contention. They merely append "disputed evidence" to an unspecified set of communications after 2004. Accordingly, the Court finds Plaintiffs' contention immaterial to the fraud analysis.

4. Rescission

"Rescission is an equitable remedy and only available in limited circumstances." *Walter v. Holiday Inns, Inc.*, 784 F. Supp. 1159, 1166 (D.N.J. 1992) (citing *Hilton Hotels Corp. v. Piper Co.*, 214 N.J. Super. 328, 336 (1986)). It is a remedy that is "generally only available when the party seeking to rescind can restore the other party to the *status quo ante*." *Id.* "Leaving aside those circumstances where the parties consent, contracts may only be rescinded where there is either original invalidity, fraud, failure of consideration or a material breach or default." *Hilton Hotels*, 214 N.J. Super. at 336.

Both parties agree that the basis for rescission is Plaintiffs' fraud claim. (Summ. J. Mot. 20:18; Summ. J. Opp'n 22:19.) Because Plaintiffs' fraud claim fails for the reasons discussed above, the Court **GRANTS** Defendant summary judgment and **DISMISSES** Plaintiffs' request for the equitable remedy of rescission.

14 IV. CONCLUSION & ORDER

In light of the foregoing, the Court **DENIES** Plaintiffs' motion to amend their complaint (Doc. 57), and **GRANTS** Defendant's motion for summary judgment (Doc. 50).

IT IS SO ORDERED.

DATED: January 24, 2012

M. James Lorenz
United States District Court Judge

23 COPY TO:

24 HON. BERNARD G. SKOMAL UNITED STATES MAGISTRATE JUDGE

ALL PARTIES/COUNSEL